DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SP 99P-2733 /CP 1

NOV 5 1999

B. Zimmerman
Regulatory Affairs
Wildlife Pharmaceuticals
1401 Duff Drive Suite 600
Ft. Collins, Colorado 80524

Dear Ms. Zimmerman:

We refer to your suitability petition dated August 8, 1999, and filed August 12, 1999, in which you requested permission to submit an abbreviated new animal drug application (ANADA) to provide for the use of Wildlife Pharmaceutical's generic ketamine hydrochloride, which is indicated for use intramuscularly as an anesthetic in cats and as an immobilizing agent in subhuman primates. The proposed generic differs in strength from the pioneer product, Fort Dodge Animal Health's Vetalar®/Ketaset® (NADA 45-290).

The suitability petition is denied.

The proposed generic contains 200 mg/mL ketamine for IM use in cats and subhuman primates, whereas the pioneer product contains 100 mg/mL ketamine for IM use in cats and subhuman primates – a twofold difference. This petitionable change would allow use of a smaller volume to achieve the same dose. This raises concerns of safety especially for smaller animals that would be administered a small volume of drug product. The labeling cautions that respiratory depression and other adverse events may occur. We have concerns that the relationships between volume injected, and the effects on duration of anesthesia and restraint, and any adverse events may not be predictable. Therefore, because a twofold increase in strength raises questions of safety, studies other than bioequivalence will be required to demonstrate the safety and/or effectiveness of ketamine injection for the intended uses in cats and subhuman primates.

Section 512(n)(3)(C) of the Federal Food Drug and Cosmetic Act provides for a suitability petition to be denied if investigations must be conducted to show the safety and effectiveness, in animals to be treated with the drug, of the strength of the proposed product when it differs from the strength of the approved new animal drug. Because investigations beyond bioequivalence are required for approval of your proposed product, the suitability petition is denied and the product is ineligible for consideration under an ANADA. A new animal drug application would be required to obtain approval of your proposed product.

If you disagree with our denial of your suitability petition, you may petition for reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Such a

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petition is based solely on the information and views contained in your original petition and is submitted in accordance with § 10.20 in the format outlined in § 10.33. The petition for reconsideration is submitted no later than 30 days after the date of this denial of the suitability petition, and should be filed with the Dockets Management Branch, Food and Drug Administration, HFA-305, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please refer to the docket number cited above in any submission regarding this original suitability petition.

If there is additional information not included as part of your original submission that you would like the agency to consider, you should submit a new petition including all the necessary information, to the Dockets Management Branch at the address noted above.

You may also be aware of the recent classification of ketamine as a Schedule III substance (Federal Register, July 13, 1999; 64 FR 37673). The reclassification will affect the handling and manufacturing controls for the drug product.

You may contact Dr. Elizabeth A. Luddy, Acting Director, Division of Therapeutic Drugs for Non-Food Animals, (301) 827-7540, for any questions on the specific requirements for the NADA submission.

Sincerely yours,

Claire M Lathers 11/5/99

Claire M. Lathers, Ph.D., F.C.P.
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine